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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Registration and Listing and MDR Baseline Reporting Grassroots Meetings for Medical Device Manufacturers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meetings.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following two open public meetings: Registration and Listing and MDR Baseline Reporting Grassroots Meetings for Medical Device Establishments. The topics to be discussed are FDA's intention to propose changes to the current medical device registration and listing process, and Medical Device Reporting (MDR) baseline reporting process. These meetings are being conducted to provide a forum in which FDA can obtain industry views on changes to the device registration and listing system that FDA is currently considering. The changes being considered are aimed at streamlining the collection of registration and listing data, improving the accuracy and quality of the data in the system, and decreasing the time it takes establishments to register and list their devices, while ultimately reducing FDA's cost of maintaining the registration and listing system. Additional changes being considered are aimed at streamlining the collection of MDR baseline information by making this data a part of the device listing process, rather than the MDR data collection process.

DATES: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: See Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

For general meeting program information: Bryan H. Benesch, Office of Compliance (HFZ–300), Center for Devices and Radiological Health, Food and Drug Administration, 2094

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Gaither Rd., Rockville, MD 20850, 301–594–4699 ext. 122, FAX 301–594–4610, e-mail: BHB@CDRH.FDA.GOV.

For registration information about the Dallas meeting: Ms. Melissa Crabtree, Food and Drug Administration, 7920 Elmbrook Rd., suite 102. Dallas, TX 75247–4982, FAX 214–655–8114.

For registration information about the Irvine meeting: Ms. Marcia Madrigal, Pacific Region, Food and Drug Administration, 1301 Clay St., suite 1180N, Oakland, CA 94612–5217, FAX 510–637–3977.

Persons interested in attending a meeting should fax their registration to either Ms. Crabtree (Dallas) or Ms. Madrigal (Irvine), including your name and position/title, firm name, address, telephone and fax number. There is no charge to attend either meeting, but advance registration is requested due to a maximum number of 65 attendees per meeting; walk-in registrations may not be accommodated. If you need special accommodations due to a disability, please contact the appropriate person at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

Over the past 3 years, FDA has reviewed the entire registration and listing process to determine how the process can be made more efficient and accurate. This was one of many reengineering efforts conducted by the Center for Devices and Radiological Health (CDRH). This reengineering effort has resulted in a number of suggestions aimed at improving the registration and listing process for both FDA and industry. These meetings will help FDA obtain the medical device industry perspective on the changes under consideration and suggestions for additional changes. FDA has held four meetings on the same subject. These meetings took place on April 20 and 21, 1999, in California, May 25, 1999, in Rockville, MD, and on July 15, 1999, in Minneapolis, MN.

Some of the changes that FDA is currently considering include the following:

(1) Require industry submission of registration and listing information through the CDRH Internet site. What are the advantages and disadvantages to industry, and how would industry be affected if Internet based submissions are mandated?

(2) Require that parent companies register as establishments.

(3) Require that additional data elements be submitted to FDA, e.g., premarket submission numbers for those devices that have gone through the premarket notification (510(k)), humanitarian device exemption, premarket approval, or product development protocol processes.

(4) Because of the ease of submission through the CDRH Internet site, require that firms register and list within 5 days (current requirement is 30 days) of entering into an operation that requires registration and listing.

A summary report of each meeting will be available on CDRH's Internet site approximately 60 working days after each meeting. The CDRH Registration and Listing Process Reengineering Team home page may be accessed at http://www.fda.gov/cdrh/grassroots/reglist.htm.

The Office of Management and Budget (OMB) has requested FDA look at other options for the collection of the baseline data elements required by 21 CFR 803.55 of the Medical Device Reporting (MDR) regulation. This was, in part, initiated by letters from AdvaMed (formerly the Health Industry Manufacturers Association) pointing out some redundancies in information collection. Manufacturer baseline data are currently submitted to the FDA on Form 3417 and requests product information for the specific device. Some of these data elements are also collected under the Medical Device Registration and Listing regulation, 21 CFR part 807.

FDA is considering requesting some data elements found on the baseline form through an Internet site interface that will allow the device industry to register and list electronically. In an effort to eliminate duplicative reporting and provide for a more efficient data collection process, CDRH is exploring the idea that, for MDR purposes, model level device information could also

be collected as part of the proposed registration and listing process. The authority to regulate the requirements imposed upon manufacturers who submit baseline reports would remain in § 803.55.

TABLE 1.—MEETING SCHEDULES

Meeting Address	Dates	Times
Dallas Meeting, Radisson Hotel Dallas,1893 West Mockingbird Lane, Dallas, TX 75235, 214–634–8850.	Tuesday, September 19, 2000	Registration: 8 a.m. Meeting: 8:30 a.m. to 12:30 p.m.
Irvine Meeting, Food and Drug Administration, Los Angeles District Office, 19900 MacArthur Blvd., suite 300, Irvine, CA 92612, 949–798–7714.	Wednesday, September 20, 2000	Registration: 8 a.m. Meeting: 8:30 a.m. to 12:30 p.m.

Dated: 8/10/00

August 10, 2000

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